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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC.,)
Plaintiff,)
v.)
NOVITIUM PHARMA, LLC,)
Defendant.)
C.A. No. _____
Document Filed Electronically

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

For its Complaint against Defendant Novitium Pharma, LLC (“Novitium” or “Defendant”), Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity” or “Plaintiff”), by and through its attorneys, alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for declaratory judgment of patent infringement of United States Patent Nos. 11,040,023 (the “023 patent”) and 11,141,405 (the “405 patent”) (collectively the “Patents-in-Suit”) under the patent laws of the United States, Title 35, United States Code, that arises out of Novitium’s imminent manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the product that is the subject of Bionpharma Inc.’s (“Bionpharma”) ANDA No. 212408 (“Novitium Formulation”) prior to the expiration of the Patents-in-Suit. Azurity seeks all available relief under

the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and any other applicable laws for Novitium's infringement of the Patents-in-Suit.

THE PARTIES

2. Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn MA 01801.

3. On information and belief, Novitium is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 70 Lake Drive, East Windsor, NJ 08520. On information and belief, Novitium is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.*, and from Novitium's imminent manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the Novitium Formulation before the expiration of the Patents-in-Suit.

5. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) (patent infringement), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Novitium because, among other things, on information and belief, Novitium is a corporation with its principal place of business in New Jersey.

7. Venue is proper in this Court under 28 U.S.C. § 1391(c).

8. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Novitium's infringement of the Patents-in-Suit, given that Novitium is and/or is poised to manufacture, use, sell, import, and/or

offer to sell and/or induce or contribute to others doing the foregoing within the United States of the Novitium Formulation before the expiration of the Patents-in-Suit.

9. On information and belief, the Novitium Formulation is the same formulation as the previous formulation sold by Bionpharma and its previous manufacturer, CoreRx, Inc. (“CoreRx”) (“the ANDA Formulation”). On information and belief, the Novitium Formulation is therefore also the alleged infringing product at issue in two other pending litigations in the United States District Court for the District of Delaware and one pending litigation in the United States District Court for the Middle District of Florida. *See Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.); *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.); and *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 22-784-SDM-AAS (M.D. Fla.).

AZURITY’S EPANED® PRODUCT

10. Azurity holds approved NDA No. 208686 for a ready-to-use oral solution of enalapril maleate, which is prescribed and sold under the trade name Epaned®.

11. Azurity’s Epaned® product is the first FDA approved ACE inhibitor treatment that is a ready-to-use oral solution. Epaned® is approved for hypertension in children one month of age and older and is also indicated to treat hypertension, heart failure, and asymptomatic left ventricular dysfunction in adults.

PATENTS-IN-SUIT

12. The ’023 Patent, entitled “Enalapril Formulations,” issued on June 22, 2021. A true and correct copy of the ’023 Patent is attached to this Complaint as Exhibit A.

13. The ’023 Patent was duly and legally issued to Azurity as the assignee and Azurity owns all rights, title and interest in the ’023 patent.

14. Pursuant to 21 U.S.C. § 355, the ’023 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Azurity’s Epaned® product.

15. The ’023 patent describes stable, oral liquid formulations of enalapril.

16. The '023 patent expires on March 25, 2036.

17. The '405 patent, entitled "Enalapril Formulations," issued on October 12, 2021. A true and correct copy of the '405 patent is attached to this Complaint as Exhibit B.

18. The '405 patent was duly and legally issued to Azurity as the assignee and Azurity owns all rights, title, and interest in the '405 patent.

19. Pursuant to 21 U.S.C. § 355, the '405 patent is listed in the Orange Book in connection with Azurity's Epaned® product.

20. The '405 patent describes stable, oral liquid formulations of enalapril.

21. The '405 patent expires on March 25, 2036.

INFRINGEMENT BY NOVITIUM

22. On information and belief, Novitium has engaged in concrete steps to infringe the Patents-in-Suit, with the intent to conduct infringing activity. On information and belief, Novitium manufactures, offers to sell, and sells or is poised to manufacture, offer to sell, and sell the Novitium Formulation.

23. Novitium has represented through an official disclosure to the National Institute of Health that it is the manufacturer of the Novitium Formulation for Bionpharma. Ex. C at 14.¹

24. On information and belief, the Novitium Formulation is the same as the ANDA Formulation. *See* Ex. C at 14.

25. On June 22, 2021, Azurity brought an action against Bionpharma alleging that the filing of ANDA No. 212408 was an act of infringement of the '023 patent because the ANDA Formulation, and thus the Novitium Formulation, is covered by one or more claims in the '023 patent. That case is captioned *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.) ("the '023 Bionpharma Action").

26. On information and belief, Novitium is aware of the '023 Bionpharma Action.

¹ This information is available through the National Institute of Health's website at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9391b8d8-2217-4838-8976-1a5ad90ef4ca&type=display>

27. On October 15, 2021, Azurity brought an action against Bionpharma for infringement of the '405 patent. That case is captioned *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.) ("the '405 Bionpharma Action").

28. On information and belief, Novitium is aware of the '405 Bionpharma Action.

29. On April 1, 2022, Azurity brought an action against CoreRx for infringement of the '023 and '405 patents. That case is captioned *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 22-784-SDM-AAS (M.D. Fla.) ("the CoreRx Action"). CoreRx has manufactured the ANDA Formulation and sold it to Bionpharma. Ex. C.

30. On information and belief, Novitium is aware of the CoreRx Action.

31. The Patents-in-Suit expire on March 25, 2036.

32. On August 10, 2021, several weeks after the '023 patent legally issued from the United States Patent and Trademark Office and Azurity brought suit for infringement of the '023 patent against Bionpharma, ANDA No. 212408 was approved by FDA and Bionpharma and CoreRx began selling the ANDA Formulation.

33. Now, over a year after the '023 patent issued and nearly a year after the '405 patent issued, on information and belief, in June 2022, in blatant disregard for Azurity's patent rights, Novitium has listed itself as the manufacturer of the Novitium Formulation, which, on information and belief, it intends to manufacture, offer to sell, and sell.

34. On information and belief, the Novitium Formulation has been approved by FDA and Novitium has begun and/or will begin manufacturing, offering to sell, and selling the Novitium Formulation to Bionpharma.

35. On or about December 1, 2021, CoreRx stopped supplying the ANDA Formulation to Bionpharma. Ex. D. On December 13, 2021, Bionpharma's President and CEO, Venkat Krishnan, stated in a declaration signed under penalty of perjury that it would take at least nine months for Bionpharma to obtain a new supplier and transfer the product to a new manufacturer. Ex. E at ¶ 34. At the time, Bionpharma was "currently engaged" in obtaining a new supplier. *Id.* Now, ten months from this declaration, it is clear Novitium is that new supplier. *See* Ex. C at 14.

36. On information and belief, Bionpharma is no longer selling the ANDA Formulation previously supplied by CoreRx and will begin selling the Novitium Formulation. Bionpharma's President and CEO, Venkat Krishnan stated in a declaration signed under penalty of perjury, "Bionpharma will exhaust its inventory of [the ANDA Formulation] before" it obtains a new supplier. Ex. F at ¶ 3. Bionpharma requested a preliminary injunction against CoreRx to get it "over the hump" from one supplier to the next. Ex. G at 3:25-4:1, 4:6-13, 5:4-8. On information and belief, Bionpharma has sold through its supply of the ANDA Formulation and Novitium is and/or is poised to manufacture, offer to sell, and sell to Bionpharma the Novitium Formulation and has made substantial and meaningful preparations to do so.

37. On information and belief, Novitium has engaged and/or is poised to engage in the commercial manufacture, offer for sale, and sale of the Novitium Formulation before the expiration of the Patents-in-Suit with the knowledge and intent to infringe the Patents-in-Suit.

38. On information and belief, the Novitium Formulation infringes at least one claim of the Patents-in-Suit, including at least claim 1 of the '023 patent and claim 1 of the '405 patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

CLAIMS FOR RELIEF

Count I

(Declaratory Judgment of Infringement of the '023 Patent Under 35 U.S.C. § 271(a)-(c))

39. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

40. On information and belief, Novitium, as the named manufacturer for the Novitium Formulation, intends to engage in and/or induce another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation and has made and will continue to make substantial and meaningful preparations to do so. Novitium's planned acts of infringement will irreparably injure and damage Azurity.

41. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality

to warrant the issuance of a declaratory judgment concerning whether the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation in the United States will be an act of direct infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(a), including at least claim 1 of the '023 patent.

42. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether Novitium will induce infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(b) by inducing the making, using, offering to sell, selling, and/or importation of the Novitium Formulation in the United States. On information and belief, Novitium will intentionally encourage such acts of direct infringement with knowledge of the '023 patent and knowledge that its acts will encourage infringement.

43. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether Novitium will contributorily infringe one or more claims of the '023 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Novitium Formulation in the United States. On information and belief, Novitium, through offering to sell or selling the Novitium Formulation, will offer to sell within the United States or import into the United States a component of a composition or material for use in practicing one or more claims of the '023 patent. On information and belief, Novitium will conduct such activities knowing such component of a composition or material to be especially adapted for a use that infringes one or more claims of the '023 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

44. The foregoing actions by Novitium will constitute infringement of the '023 patent.

45. Novitium will commit those acts of infringement without license or authorization.

46. Novitium will commit those acts of infringement despite its knowledge of the '023 patent, the '023 Bionpharma Action, and the CoreRx Action.

47. Azurity is entitled to a declaratory judgment that Novitium's commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation would infringe the '023 patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. Accordingly, there is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Azurity is entitled to a prompt and definitive judicial determination that the Novitium Formulation infringes at least one claim of the '023 patent. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

49. As a result of such declaratory judgment, Novitium's infringement should be enjoined because the irreparable harm to Azurity resulting from such infringement would leave Azurity without an adequate remedy at law.

Count II

(Declaratory Judgment of Infringement of the '405 Patent Under 35 U.S.C. § 271(a)-(c))

50. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

51. On information and belief, Novitium, as the named manufacturer for the Novitium Formulation, intends to engage in and/or induce another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation and has made and will continue to make substantial and meaningful preparations to do so. Novitium's planned acts of infringement will irreparably injure and damage Azurity.

52. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation in the United States will be an act of direct infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(a), including at least claim 1 of the '405 patent.

53. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether Novitium will induce infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(b) by inducing the making, using, offering to sell, selling, and/or importation of the Novitium Formulation in the United States. On information and belief, Novitium will intentionally encourage such acts of direct infringement with knowledge of the '405 patent and knowledge that its acts will encourage infringement.

54. There is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether Novitium will contributorily infringe one or more claims of the '405 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Novitium Formulation in the United States. On information and belief, Novitium, through offering to sell or selling the Novitium Formulation, will offer to sell within the United States or import into the United States a component of a composition or material for use in practicing one or more claims of the '405 patent. On information and belief, Novitium will conduct such activities knowing such component of a composition or material to be especially adapted for a use that infringes one or more claims of the '405 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

55. The foregoing actions by Novitium will constitute infringement of the '405 patent.

56. Novitium will commit those acts of infringement without license or authorization.

57. Novitium will commit those acts of infringement despite its knowledge of the '405 patent, the '405 Bionpharma Action, and the CoreRx Action.

58. Azurity is entitled to a declaratory judgment that Novitium's commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation would infringe the '405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

59. Accordingly, there is an actual, substantial, and continuing justiciable case or controversy between Azurity and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Azurity is entitled to a prompt and definitive judicial determination that the Novitium Formulation infringes at least one claim of the '405 patent. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

60. As a result of such declaratory judgment, Novitium's infringement should be enjoined because the irreparable harm to Azurity resulting from such infringement would leave Azurity without an adequate remedy at law.

PRAYER FOR RELIEF

Azurity respectfully requests the following relief:

- a) A declaration that Novitium's making, using, offering to sell, or selling in the United States, or importing into the United States of the Novitium Formulation would constitute infringement of one or more claims of the Patents-in-Suit and/or induces or contributes to the infringement of one or more claims of the Patents-In-Suit 35 U.S.C. § 271(a), (b) and/or (c);
- b) A judgment that Novitium's making, using, offering to sell, or selling in the United States, or importing into the United States of the Novitium Formulation would constitute infringement of one or more claims of the Patents-in-Suit and/or induces or contributes to the infringement of one or more claims of the Patents-In-Suit 35 U.S.C. § 271(a), (b) and/or (c);
- c) A permanent injunction enjoining Novitium, and its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture use, offer to sell, or importation into the United States, of any drug product covered by the Patents-in-Suit, including the Novitium Formulation, until the expiration of the Patents-in-Suit;
- d) An award of the costs and expenses Azurity has incurred in this action; and

e) An award of any such other and further relief as the Court may deem just and proper.

Dated: October 3, 2022

Respectfully submitted,

SAIBER LLC
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Azurity Pharmaceuticals, Inc.

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel hereby certifies that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding, except *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.); *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.); and *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 22-784-SDM-AAS (M.D. Fla.).

Dated: October 3, 2022

Respectfully submitted,

SAIBER LLC
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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiff Azurity Pharmaceuticals, Inc. hereby certifies that it seeks injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 3, 2022

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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